REQUEST FOR EXTENSION OF TIME

In accordance with 37 C.F.R. 1.17(a) and 1.136(a), applicants request a one month extension of the term to reply, i.e. up to and including May 7, 2001. A check for $110.00 is enclosed for the time extension. The Commissioner is hereby authorized to charge any additional fee required by this paper, or the extension of time, or credit any overpayment to Deposit Account No. 50-0320.

REMARKS

The Office Action required restriction from among the following Groups under 35 U.S.C. §§ 121 and 372:

Group I: Claims 1-3, 9-16, 30-33, 39-46, and 60-64, drawn to an immunogenic composition comprising a PCV-2 immunogen, classified in class 424, subclass 184.1;

Group II: Claims 1-4, 12-16, 30-34, 42-46, and 60-64, drawn to a polypeptide comprising an epitope of a PCV-2 antigen, classified in class 424, subclass 184.1;

Group III: Claims 1-3, 5, 12-16, 30-33, 35, 42-46, and 60-64, drawn to an immunogenic composition comprising an antibody elicited by a PCV-2 immunogen, classified in class 424, subclass 139.1.;

Group IV: Claims 1-3, 6, 12-16, 30-33, 36, 42-46, and 60-64, drawn to an immunogenic composition comprising an antibody elicited by an epitope of a PCV-2 immunogen, classified in class 424, subclass 139.1;

Group V: Claims 1-3, 7, 9-11, 17-29, 31-33, 37, 39-41, and 43-64, drawn to an immunogenic composition comprising a vector expressing a PCV-2 immunogen, classified in class 435, subclass 320.1;

Group VI: Claims 1-3, 8-11, 13-29, 31-33, 38-41, and 43-64, drawn to an immunogenic composition comprising a vector expressing an epitope of a PCV-2 immunogen, classified in class 435, subclass 320.1;

Group VII: Claims 1-3, 12-16, 30-33, 42-46, and 60-64, drawn to an immunogenic composition comprising a PCV-1 immunogen that binds to an antibody elicited by a PCV-2 immunogen or epitope, classified in class 424, subclass 136.1;

Group VIII: Claims 1-3, 12-16, 30-33, 42-46, and 60-64, drawn to immunogenic composition comprising a polypeptide comprising an epitope of a PCV-1 immunogen that also binds to an antibody that elicits a PCV-2 immunogen or epitope, classified in class 424, subclass 184.1;

Group IX: Claims 1-3, 12-16, 30-33, 42-46, and 60-64, drawn to immunogenic composition comprising an antibody elicited by a PCV-1 immunogen that binds with a PCV-1 immunogen/epitope and a PCV-2 immunogen/epitope, classified in class 424, subclass 130.1;

Group X: Claims 1-3, 12-16, 30-33, 42-46, and 60-64, drawn to immunogenic composition comprising an antibody elicited by an epitope of a PCV-1 immunogen that binds to a PCV-1 immunogen/epitope and an epitope of a PCV-1 immunogen that binds with a PCV-2 immunogen/epitope, classified in class 424, subclass 159.1.

Group XI: Claims 1-3, 9-11, 13-29, 31-33, 38-41, and 43-64, drawn to immunogenic composition comprising a vector that expresses a PCV-1 immunogen that also binds to an antibody elicited by a PCV-2 immunogen/epitope, classified in class 435, subclass 320.1;

Group XII: Claims 1-3, 9-11, 13-29, 31-33, 38-41, and 43-64, drawn to immunogenic composition comprising a vector expressing an epitope of a PCV-1 immunogen that also binds to an antibody elicited by a PCV-2 immunogen/epitope, classified in class 424, subclass 130.1;

Group XIII: Claims 65 and 66, drawn to a method of making an immunogenic composition, classified in class 435, subclass 69.1, 71.1, or 480;

Group XIV: Claims 67, 68, 70, 72, 73, and 76-81, drawn to an isolated nucleic acid, classified in class 536, subclass 23.1;

Group XV: Claims 69, 71, 74, and 75 drawn to a vector comprising a nucleic acid, classified in class 424, subclass 320.1.

Applicants elect Group V, with traverse.

It is respectfully requested, for the following reasons, that the restriction requirement be reconsidered and withdrawn and the Examiner conduct a complete search, examination and

prosecution of the subject matter claimed in Groups I-XV—as they all relate to a single invention on the basis of the following traverse.

The Office Action contends that the inventions in Groups I-XII, XIV and XV are distinct because they are directed towards different products—namely, polynucleotides, polypeptides and antibodies— that all require separate fields of search. The Office Action further asserts that the products of each Group are independent because synthesis of each product is possible by chemical means. Thus, each requires a different search placing an undue burden on the Examiner.

The Office Action also states that Groups I-XII, XIV and XIII are related as a process of making and product made, but simultaneously asserts that Groups I-XII, XIV and XV are distinct because the different processes used to obtain the compositions pertaining to Groups I-XII and XIV can be used to make a variety of different compounds.

It is respectfully submitted, however, that the allegations in the Office Action are misplaced.

Under 35 U.S.C. § 121, if there are two or more independent and distinct inventions in one application, the application may be restricted to one of the inventions. Inventions are "independent" if there are no distinct relationships between two or more subjects disclosed (MPEP 802.01). The term "distinct" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER." (MPEP 802.01, July 1988) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following is present (MPEP 808.02):

1. Separate classification;
2. Separate status in the art; or
3. Different field of search.

Under Patent Office examining procedures, "[i]f the search and examination of an entire

application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803) (emphasis added).

The Office Action fails to justify why a separate examination and search of 15 Groups of claims is necessary. All of the claims represent a web of knowledge and continuity of effort that merits examination in a single application. Further, to search or examine these Groups together does not pose a serious burden on the Examiner. Rather, the 15-way restriction requirement imposes a severe hardship on both the USPTO and Applicants; namely, overlapping searches and examinations by the USPTO in at least 15 applications, and the need to re-file this application at least fourteen more times, for a total of 15 applications. The cost and expense of the restriction requirement is unduly burdensome.

Contrary to the Office Action, Groups I-XII, XIV, and XV are clearly related to each other as compositions that provide a desired immunological response to PCV-2. Groups I-XII, XIV and XV all form a single general inventive concept under the PCT Rules and Examples. For instance, Example 4 of Annex B, Part 2, of the PCT Administrative Instructions (Appendix A1 of the MPEP at A1-40) provides:

> Claim 1: Use of a family of compounds X as insecticides.
>
> Claim 2: Compound X_1 belonging to family X.
>
> Provided X_1 has the insecticidal activity and the special technical feature in claim 1, unity is present.

Similar to the example above, each of the products in Groups I-XII, XIV and XV belong to a family of compositions that elicit an immunogenic response to PCV-2. Each product, standing alone, has the special technical feature of eliciting the desired immune response. Thus, a search of Groups I-XII, XIV and XV together does not unduly burden the examiner.

Furthermore, Group V and Group VI are within the same class and subclass and should be rejoined. The search and examination Group V — namely, a vector expressing a PCV-2 immunogen— clearly encompasses Group VI, a vector expressing an epitope of a PCV-2

immunogen, such that there is no undue burden or justification for separating Groups V and VI. Clearly, Groups V and VI should be rejoined.

Group XIII is drawn to a method of making the immunogenic compositions set forth in Groups I-XII and XIV. As the Office action admits, Groups I-XII, XIV and XIII are clearly related as a process of making and a product thereof. The Office Action fails to demonstrate adequately that the immunogenic compositions comprising Groups I-XII, XIV and XV can be made by a materially different process. Therefore, search of Groups I-XII, XIV and XV would not unduly burden the Examiner.

The Office Action's allegation that Groups I-XV cover divergent subject matter, overlooks the more prevalent commonalties of the technology. Examination of any one of Groups I-XV compels consideration of the patentability of each of the other Groups. Note again the above-stated relationship between Groups V and VI, which patently supports rejoinder of Groups V and VI. It is respectfully submitted that the allegations in the Office Action are erroneous. It is not burdensome to consider Ggroups I-XV together as they all relate to a single invention.

Furthermore, as alluded to earlier, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, a shortened patent term may result in any divisional or continuing applications filed). Restriction is not proper, especially since the Office Action fails to present the requisite showing of either a serious burden or a lack of unity. Moreover, there are relationships between the claims of all the Groups. Indeed, the search and examination of each Group is likely to be co-extensive and, in any event, would involve such interrelated art that search and examination of the entire application is possible without undue burden on the Examiner. All of the preceding, therefore, mitigates against restriction.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the restriction requirement, as it is not unduly burdensome to search and examine Groups I-XV, and because Unity of Invention exists among Groups I-XV.

If the Requirement for Restriction is not reconsidered and withdrawn, it is respectfully requested that consideration be especially given to regrouping the claims such that prosecution of the claims comprising Groups V and VI —namely the claims drawn to the immunogenic composition comprising a vector expressing a PCV-2 immunogen and a vector expressing a PCV-2 epitope —be in this application, especially as they are both in class 435, subclass 320.1.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the Requirement for Restriction. Alternatively, Applicants respectfully request a reconstituting of the Restriction Requirement.

If any fee is determined to be due for consideration and entry of this response, the Assistant Commissioner is authorized to charge the fee therefor or credit any overpayment to Deposit Account No. 50-0320

Early and favorable examination on the merits of all of the claimed subject matter, or at least of Groups V and VI, is earnestly solicited.

Respectfully submitted,
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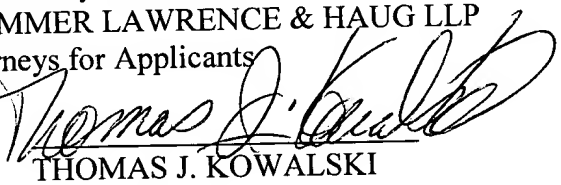
By: 

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